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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	
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12/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,545	FERRANDIS, ERIC	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 18-22* is/are pending in the application.

4a) Of the above claim(s) *6,7,11,18 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-10 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11 and 18-22 are all the pending claims for this application.

Election/Restrictions

2. The Examiner respectfully apologizes for the error in the Office Action of 9/21/07 which inadvertently included Claim 18 in Group I and which was also restricted into Group IV as a separate invention. The reasons for the invention of Claims 1-5, 8-10, 12 and 14 (Group I) being patentably distinguishable from the invention of Claim 18 (Group IV) is herein incorporated.

3. Applicant's election of Group I (Claims 1-5, 8-10, 12 and 14) in the reply filed on 10/16/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 6, 7, 11, 18 and 20-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/16/07.

5. Claims 1-5, 8-10, 12 and 14 are all the pending claims under examination.

Information Disclosure Statement

6. The foreign patent reference cited in the IDS of 5/18/07 has been considered and entered.

Specification

7. The specification is objected to for failing to cross-reference the priority documents for the instant application.

8. The use of trademarks (e.g., Superscript®) has been noted in this application. A trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants are requested to carefully check the entire specification for any other improperly identified trademarks.

Claim Objections

9. Claim 10 is objected to for the following apparent typographical errors:

a) at line 5, "immunoligical an./or" should recite "immunological and/or";

b) at line 8, "o host cell transformed or transfected" should recite "a host cell transformed or transfected";

c) at line 14, "protein human GHRN" should recite "human GHRN protein" or "protein binding human GHRN."

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 4 and 5 are rejected under 35 U.S.C. 101 because the claims read on the polynucleotide per se which is found in narture. Products of nature do not constitute patentable subject matter as defined in 35 U.S.C. 101. See MPEP 2105. Since a polynucleotide does not exist in nature in a purified form, it is suggested that Applicants use the language "isolated' or "purified" in connection with the polynucleotide to identify a product not found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 10 and 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1 and 19 are indefinite for the recitation "or one of its fragments" in Claim 1 because it is not clear if the fragment is referring to a fragment of the polynucleotide or a fragment of the sequence SEQ ID NO:8.

b) Claim 10, lines 3 and 12 is indefinite for the recitation "or one of the fragments of the latter" because it is not clear if the phrase is referring to the sequence of SEQ ID NO: 9 or SEQ ID NO:13 or both.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

12. Claims 1, 10 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotide fragments of a polynucleotide comprising SEQ ID NO: 8 (Claim 1) or polynucleotide fragments of a polynucleotide comprising SEQ ID NO: 9 or SEQ ID NO:13 (Claim 10) or a pharmaceutical composition comprising polynucleotide fragments of a polynucleotide comprising SEQ ID NO: 8 of Claim 1 (Claim 19).

The specification discloses the cloning and isolation of the gene for heterocarpine which is a plant-derived ligand from Pilocarpus heterophyllus which binds to human growth hormone releasing hormone (GHRH). The specification discloses the following sequences corresponding to hGHRH:

SEQ ID NO:8- cDNA for heterocarpine (p. 28);

SEQ ID NO:9- open reading frame of cDNA for heterocarpine (p. 30); and

SEQ ID NO:13- SEQ ID NO:9 having artificially undergone deletion of the initiation codon ATG and the stop codon (p. 34);

The sequences SEQ ID NOS: 4/5 and SEQ ID NO:11/12 are disclosed as being primers used in PCR reactions for heterocarpine cloning (p. 10, lines 14-16).

The specification makes a general disclosure for isolated fragments of a "polynucleotide being such that it encodes a polypeptide having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation" [0006]. The specification does not provide sufficient written description as to the structural features of the claimed genus of polynucleotide fragments for the polynucleotides comprising SEQ ID NOS: 8, 9 or 13 (or encoded polypeptides) and the correlation between the chemical structure and function of the genus of polynucleotide fragments, such as structural domains or motifs that are essential and distinguish members of the genus from those excluded. The specification does not disclose a single polynucleotide species with less than 100% sequence identity for the sequence of SEQ ID NO: 8, 9 or 13 (or encoded polypeptides).

A "representative number of species" means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if

the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]. "See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)(Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.).

It has been well known that minor structural differences even among structurally related compounds can result in substantially different biology, expression and activities. Based on the instant disclosure one of skill in the art would not know which sequences are essential, which sequences are non-essential and what particular sequence lengths identify essential sequences for identifying a polynucleotide fragment encompassed by the claimed specificity. For example, there is insufficient guidance based on the reliance of disclosure of SEQ ID NO:8, 9 or 13 to direct a person of skill in the art to select or to predict particular sequences as essential for identifying

polynucleotide fragments encompassed by the claimed specificities. Mere idea of function is insufficient for written description; isolation and characterization at a minimum are required.

In the absence of sufficient guidance and direction to the structural and functional analysis, applicant's reliance on the activity of the heterocarpine encoded by SEQ ID NO:1, 2 or 3 disclosed in the specification as-filed does not appear to provide sufficient written description for the genus of polynucleotide fragments encompassed by the claimed specificities in view of the above evidence, which indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.

For inventions in an unpredictable art, adequate written description of a genus, which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case, applicant has not even disclosed a single species encompassed by the highly variant genus nor is there disclosure of the common attributes or features (i.e., structural domains) that are essential for activity or those which are non-essential. See, e.g., Eli Lilly. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddles v.Baird*, 30 USPQ2d 1481, 1483. In *Fiddles v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides of SEQ ID NO: 8, 9 and 13, but not the full breadth of the claim for any polynucleotide fragment, meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Scope of Enablement

13. Claims 1, 10 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides comprising SEQ ID NO: 8, 9 or 13 encoding the heterocarpin protein and a process for isolating a recombinant heterocarpin protein encoded by the polynucleotide of SEQ ID NO: 9 or 13, does not reasonably provide enablement for just any polynucleotide fragment of a polynucleotide comprising SEQ ID NO: 8, 9 or 13 or the protein encoded by the nucleotide fragment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability of the art, the breadth of the claims, the quantity of experimentation which would be required in order to use the invention as claimed.

Nature of the Invention/Skill in the Art

The interpretation of Claims 1, 10 and 19 is discussed supra. The relative skill in the art required to practice the invention is a molecular biologist.

Disclosure in the Specification

The interpretation of the specification with respect to the polynucleotide fragments for polynucleotides comprising SEQ ID NOS: 8, 9 or 13 is discussed supra. The specification does not provide any working examples of: 1) polynucleotide fragments encoding heterocarpin proteins having any biological activity, or 2) the functional domains for any heterocarpin proteins and polypeptides that are required to be encoded by a corresponding polynucleotide fragment. Thus the specification is strongly dispositive to one of ordinary skill in the art being enabled for making or using any polynucleotide fragments of polynucleotides comprising SEQ ID NOS: 8, 9 or 13.

The claims are not commensurate in scope with the enablement provided in the specification. The specification does not support the broad scope of the claims which encompass any size polynucleotide fragment because the specification does not disclose the following:

The specific positions and regions of the sequence(s) which can be predictably modified and which regions are critical for encoding a functional heterocarpin protein; and

The specification provides insufficient guidance as to which of the essentially infinite possible fragments is likely to be successful.

Thus, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed polynucleotide fragments in a manner reasonably correlated with the scope of the claims broadly including any number of polynucleotide fragments. The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 19 24 (CCPA 1970).

Without such guidance, the changes which can be made in the polynucleotide structure and still encode for a functional biological activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F,2d 1200, 18 USPQ 1016 (Fed. Cir. 1991) at 18 USPQ 1026 1027 and Ex parte Forman, 230 USPQ 546 (BPAI 1986).

For example, the removal of the amino terminal histidine of glucagon substantially decreases the ability of the molecule to bind to its receptor and activate adenylate cyclase (Lin et al Biochemistry USA Vol 14:1559-1563 (1975). Thus one of skill in the art could not predict which of the N- or C-terminal nucleic acids could be deleted from any one of polynucleotide comprising a sequence of SEQ ID NO : 8, 9 or 13 in order to create a fragment based on the lack of disclosure in the specification as to which domains were critical for encoding a functional heterocaptin protein.

In view of the lack of predictability of the art to which the invention pertains, the lack of disclosure for the functional domains of the heterocarptin protein of SEQ ID NO: 8, 9 or 13 and working examples of polynucleotide fragments for any one of the polynucleotides comprising the sequence of SEQ ID NO: 8, 9 or 13, one skilled in the art would be required to perform undue experimentation.

Enablement

14. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability of the art, the breadth of the claims, the quantity of experimentation which would be required in order to use the invention as claimed.

Nature of the Invention/ Skill in the Art

Claim 19 is interpreted as being drawn to a pharmaceutical composition for treating any proliferative disease comprising an effective amount of a polynucleotide of comprising SEQ ID NO:8 or a fragment thereof and an inert carrier. The claim is examined for its intended use, i.e., treating a proliferative disease.

The relative skill in the art required to practice the invention is a medical physician/veterinarian treating proliferative disorders with recombinant DNA technology.

Disclosure in the Specification

The specification contemplates treating proliferative disorders such as cancer with the polynucleotide of SEQ ID NO:8 or fragments thereof (p. 5, lines 20-21 and p. 6,

lines 25-30), but does not disclose a single working example of the polynucleotide or fragment thereof alone much less any one of the foregoing subcloned into an expression vector, where in either form, the DNA molecule was administered to a cell culture model for proliferative disorder(s) or an animal model replicating a proliferative disorder. The specification does not disclose that the polynucleotide embodiments encompassed by the claim would produce a therapeutic effect with treatment of any proliferative disorder as a therapeutic endpoint. One skilled in the art at the time of filing would not have been enabled to practice using the pharmaceutical composition to treat any proliferative disease because of the limited disclosure in the specification.

Prior Art Status: DNA gene-based therapy

The state of the art for cancer gene therapy as discussed by Vile et al (Gene Therapy, Vol. 7, pp. 2-8, 2000) is unpredictable. Vile teaches:

> The problems which gene therapy for cancer will take into the next millennium focus far less on the choice of therapeutic gene(s) to be used than on the means of delivering them. There is already a battery of genes that we know are very effective in killing cells, if they can be expressed at the right site and at appropriate levels. None the less, until the perfect vector is developed, the choice of gene will remain crucially important in order to compensate for the deficiencies of the vectors we currently have available (page 2, 1st paragraph, left column). Whatever its mechanism, no single genes can be a serious contender unless it has a demonstrable bystander effect (page 2, right column). The requirement for such a bystander effect stems directly from the poor delivery efficiency provided by current vectors (page 2, right column).
>
> A genuine ability to target delivery systems to tumor cells distributed widely throughout the body of a patient would simultaneously increase real titers and efficacy. In truth, no such systemically targeted vectors exist yet. Injection of vectors into the bloodstream for the treatment of cancer requires not only that the

> vectors be targeted (to infect only tumor cells) but also that they by protected (from degradation, sequestration or immune attack) for long periods of time so that they can reach the appropriate sites for infection. Moreover, having reached such sites, the vectors must be able to penetrate into the tumor from the bloodstream before carrying out their targeted infection (page 4, bottom left column and top right column).

In addition, Rochlitz C. F. (Swiss Medicine Weekly, 131:4-9, 2001) teaches:

> "that none of the more than one hundred clinical studies performed so far had formally proven efficacy of the approach [gene therapy] in any human disease. Although anecdotal reports of tumor responses are becoming more frequent in several human malignancies, the situation has not changed dramatically." (See page 8, bottom of page). Rochlitz continue "Main problems are still the lack of vectors with high transduction efficiency in vivo, the low tumor specificity of available systems, and our incomplete knowledge of molecular tumor pathology." (see pages 8-9).

Haupt (Exp. Biol. Med. 227:227-237 (2002)) teaches that:

> "Accumulating evidence suggests the usefulness of DNA vaccination for treating various tumors in animal models, but results from clinical trials are lacking and the therapeutic benefit in the prevention or treatment of malignancies in human beings remains to be proven." (p. 233, Col. 2, ¶1),

and

> "DNA vaccination is a promising strategy capable of inducing immune-mediated tumor reductions in animal model, but further studies are required to investigate the potential of DNA vaccination in antitumor treatment in human beings." (p. 234, Col. 1, ¶1).

Thus, at the time the application was filed, the state of the art for gene therapy was considered highly unpredictable.

Furthermore, it would take one skilled in the art an undue amount of experimentation to determine what route of administration (*e.g.* intravenous, dermal,

nasal, rectal, vaginal, inhalation, or topical administration) would result in a therapeutic response using the polynucleotide comprising the sequence SEQ ID NO:8 much less any fragment of the polynucleotide. The state of the art for the route of administration for gene therapy as exemplified by Verma, *Nature*, Vol. 389, pages 239-242, 1997, indicates that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2).

Therefore, the skilled artisan at the time the invention was made recognized the lack of predictability of the nature of the art and state of the prior art to which the instant invention pertains. Also, such disclosures clearly indicate that the amount of direction or guidance presented in the specification is limited, and would not permit a person skilled in the art to use the invention without undue experimentation at the time the invention was made.

In view of the lack of predictability of the art to which the invention pertains, the lack of established clinical protocols for effective proliferative disorders, namely, cancer therapies, undue experimentation would be required to practice using the claimed pharmaceutical composition the with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively treat any proliferative disorder and absent working examples providing evidence which is

reasonably predictive that the claimed pharmaceutical composition is effective for treating any proliferative disorder, commensurate in scope with the claimed invention.

Conclusion

15. Claims 2 and 3 are objected to as depending from a rejected base claim.

16. Claims 8 and 9 are in condition for allowance.

17. The search of the polynucleotide sequences for SEQ ID NOS: 8, 9 and 13 did not identify any other sequences have 100% identity to the polynucleotide sequences encoding the heterocarpin protein.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

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